

# OEHHA

## Office of Environmental Health Hazard Assessment

[Home](#) → [Proposition 65](#) → [Requests for Information](#) → [Trichloroethylene \(TCE\)](#)

### Proposition 65

#### REQUEST FOR RELEVANT INFORMATION ON A CHEMICAL BEING CONSIDERED FOR LISTING BY THE AUTHORITATIVE BODIES MECHANISM: TRICHLOROETHYLENE (TCE) [03/15/13]

The California Environmental Protection Agency's Office of Environmental Health Hazard Assessment (OEHHA) is requesting information as to whether trichloroethylene (TCE) meets the criteria for listing as a reproductive toxicant under the Safe Drinking Water and Toxic Enforcement Act of 1986.<sup>1</sup> This action is being proposed under the authoritative bodies listing mechanism.<sup>2</sup>

**Background on listing via the authoritative bodies mechanism:** A chemical must be listed under Proposition 65<sup>3</sup> and its implementing regulations when two conditions are met:

1. An authoritative body formally identifies the chemical as causing reproductive toxicity (Section 25306(d)<sup>4</sup>).
2. The evidence considered by the authoritative body meets the sufficiency criteria contained in the regulations (Section 25306(g)).

However, the chemical is not listed if scientifically valid data which were not considered by the authoritative body clearly establish that the sufficiency of evidence criteria were not met (Section 25306 (h)).

The U.S. Environmental Protection Agency (U.S. EPA) is one of several institutions designated as authoritative for the identification of chemicals as causing reproductive toxicity (Section 25306(l)).

OEHHA is the lead agency for Proposition 65 implementation<sup>5</sup>. After an authoritative body has made a determination about a chemical, OEHHA evaluates whether listing under Proposition 65 is required using the criteria contained in the regulations.

**OEHHA's determination:** TCE appears to meet the criteria for listing as known to the State to cause reproductive toxicity under Proposition 65, based on findings of the U.S. EPA in their document, as indicated in the table below.

Chemical	CAS No.	Endpoints	Reference	Chemical Use
Trichloroethylene (TCE)	79-01-6	Male reproductive and developmental toxicity	U.S. EPA (2011a and 2011b)	Used mainly in vapor degreasing of metal parts, also used as a solvent in the textile industry and is found in consumer products such as paint removers and adhesives.

**Formal identification and sufficiency of evidence:** In 2011, U.S. EPA updated the toxicological characterization of TCE in its Integrated Risk Information System (IRIS) entry for the chemical (U.S. EPA, 2011a). In support of the IRIS entry, a comprehensive toxicological review and summary of the available toxicological data was published (U.S. EPA, 2011b). In that document, the authoritative body reviews the scientific evidence of male reproductive and developmental toxicity and, on that basis, provides its conclusions about the potential for TCE to cause male reproductive and developmental toxicity.

#### Male Reproductive Toxicity

The U.S. EPA Toxicological Review (2011b) states that:

"The adverse effects that have been observed in both male humans and male animal models include altered sperm count, morphology, or motility (Kumar et al., 2001b; Veeramachaneni et al., 2001; Kumar et al., 2000a; Kumar et al., 2000b; Chia et al., 1996; Rasmussen et al., 1988; George et al., 1985; Land et al., 1981); decreased libido or copulatory behavior (Veeramachaneni et al., 2001; George et al., 1986; Zenick et al., 1984; Saihan et al., 1978; El Ghawabi et al., 1973; Bardodej and Vyskocil, 1956); alterations in serum hormone levels (Veeramachaneni et al., 2001; Kumar et al., 2000a; Goh et al., 1998; Chia et al., 1997); and reduced fertility (George et al., 1986). However, other studies in humans did not see evidence of altered sperm count or morphology (Rasmussen et al., 1988) or reduced fertility (Forkert et al., 2003; Sallmen et al., 1998), and some animal studies also did not identify altered sperm measures (Xu et al., 2004; Cosby and Dukelow, 1992; George et al., 1986; Zenick et al., 1984). Additional adverse effects observed in animals include histopathological lesions of the testes (Kumar et al., 2001b; Kumar et al., 2000b; George et al., 1986) or epididymides (Kan et al., 2007; Forkert et al., 2002) and altered in vitro sperm-oocyte binding and/or in vivo fertilization for TCE and/or its metabolites (DuTeaux et al., 2004a; Xu et al., 2004) (page 4-488, citations in U.S. EPA Toxicological Review (2011b)).

"In spite of the preponderance of studies demonstrating effects on sperm parameters, there is an absence of overwhelming evidence in the database of adverse effects of TCE on overall fertility in the rodent studies. That is not surprising, however, given the redundancy and efficiency of rodent reproductive capabilities. Nevertheless, the continuous breeding reproductive toxicity study in rats (George et al., 1986) did demonstrate a trend towards reproductive compromise (i.e., a progressive decrease in the number of breeding pairs producing third, fourth, and fifth litters)." (page 4-490, citations in U.S. EPA

## Toxicological Review (2011b)).

Under the Section of the U.S. EPA Toxicological Review (2011b) titled "Major Conclusions in the Characterization of Hazard and Dose Response", the authoritative body concludes that:

"Together, the human and laboratory animal data support the conclusion that TCE exposure poses a potential hazard to the male reproductive system" (page 6-9).

The document also states that:

"The human epidemiological findings and animal study evidence consistently indicate that TCE exposures can result in adverse reproductive outcomes. .... In animal studies, ... there is strong and compelling evidence for adverse effects of TCE exposure on male reproductive system and function" (page 4-487).

This appears to meet the criterion in Section 25306(d)(1) that the chemical "is the subject of a report which is published by the authoritative body and which concludes that the chemical causes.... reproductive toxicity".

**Developmental Toxicity**

The critical effects identified as the basis for the chronic oral reference dose (RfC) in the TCE IRIS entry (U.S. EPA, 2011a) and the Toxicological Review (U.S. EPA, 2011b) include developmental toxicity manifested as increased fetal cardiac malformations in rats and developmental immunotoxicity in mice following prenatal exposure. This appears to meet the criterion in Section 25306(d)(1) that the chemical "has otherwise been identified as causing ...reproductive toxicity by the authoritative body in a document that indicates that such identification is a final action".

Under the Section of the U.S. EPA Toxicological Review (2011b) titled "Major Conclusions in the Characterization of Hazard and Dose Response", the authoritative body concludes that:

"[B]ased on weakly suggestive epidemiologic data and fairly consistent laboratory animal data, it can be concluded that TCE exposure poses a potential hazard for prenatal losses and decreased growth or birth weight of offspring." (page 6-10).

"[B]ased on weakly suggestive, but overall consistent, epidemiologic data, in combination with evidence from experimental animal and mechanistic studies, it can be concluded that TCE exposure poses a potential hazard for congenital malformations, including cardiac defects, in offspring" (page 6-11).

This appears to meet the criterion in Section 25306(d)(1) that the chemical "is the subject of a report which is published by the authoritative body and which concludes that the chemical causes.... reproductive toxicity".

Scientific evidence of developmental toxicity reviewed by the authoritative body in support of these conclusions includes a number of human and animal studies. With regard to prenatal loss and effects on growth, the U.S. EPA Toxicological Review (2011b) noted that some occupational and environmental epidemiological studies reported associations between parental exposure to TCE and spontaneous abortion or perinatal death, and decreased birth weight or SGA [small for gestational age], although other studies reported mixed or null findings, and that multiple well-conducted studies in rats and mice show analogous effects of TCE exposure; i.e., pre- or postimplantation losses, increased resorptions, perinatal death, and decreased birth weight. On that basis, U.S. EPA concluded that TCE exposure poses a potential hazard for prenatal losses and decreased growth or birth weight of offspring, based on weakly suggestive epidemiologic data and fairly consistent laboratory animal data.

With regard to malformations, the U.S. EPA Toxicological Review (2011b) noted that epidemiological studies, while individually limited, as a whole show relatively consistent elevations, some of which were statistically significant, in the incidence of cardiac defects in TCE-exposed populations compared to reference groups. In laboratory animal models, avian studies were the first to identify adverse effects of TCE exposure on cardiac development, and the initial findings have been confirmed multiple times. Additionally, administration of TCE and its metabolites, TCA and DCA, in maternal drinking water during gestation has been reported to induce cardiac malformations in rat fetuses.

OEHHA evaluated the studies cited by U.S. EPA in support of its formal identification of TCE as causing male reproductive and developmental toxicity relative to the criteria in Section 25306(g). Based on the U.S. EPA Toxicological Review document (2011b), and the studies cited in that document, the criteria for listing TCE as known to cause reproductive toxicity by the authoritative bodies mechanism appear to be met.

**Request for relevant information:** OEHHA is requesting comments as to whether *trichloroethylene* meets the criteria set forth in the Proposition 65 regulations for authoritative bodies listings.

After reviewing all comments received, OEHHA will determine whether the identified chemical meets the regulatory criteria for administrative listing. If the chemical is determined to meet the listing criteria, OEHHA will proceed with the formal listing process by publishing a Notice of Intent to List.

In order to be considered, **OEHHA must receive comments by 5:00 p.m. on Tuesday May 14, 2013.** We encourage you to submit comments in electronic form, rather than in paper form. Comments transmitted by e-mail should be addressed to [P65Public.Comments@oehha.ca.gov](mailto:P65Public.Comments@oehha.ca.gov) with "DCI - trichloroethylene" in the subject line. Comments submitted in paper form may be mailed, faxed, or delivered in person to the addresses below:

Mailing Address: Ms. Cynthia Oshita  
Office of Environmental Health Hazard Assessment

P.O. Box 4010, MS-19B  
 Sacramento, California 95812-4010  
 Fax: (916) 324-6511  
 Street Address: 1001 I Street  
 Sacramento, California 95814

Comments received during the public comment period will be posted on the OEHHA web site after the close of the comment period.

**Optional public forum:** Upon request, OEHHA will schedule an informal public forum to provide individuals an opportunity to present oral comments on the possible listing of this chemical. At the forum, the public may discuss the scientific data and other relevant information related to whether the chemical meets the criteria for listing in the regulations.

The request for a public forum must be submitted in writing to Cynthia Oshita of OEHHA via email at [Cynthia.Oshita@oehha.ca.gov](mailto:Cynthia.Oshita@oehha.ca.gov) or to the attention of Cynthia Oshita at the address listed above no later than Friday, April 12, 2013. If a public forum is requested, a notice will be posted on the OEHHA web site at least ten days before the forum date. The notice will provide the date, time and location of the forum. Notices will also be sent to those individuals requesting such notification. You may sign up for electronic notices at: <http://www.oehha.ca.gov/Listservs/default.asp>

If you have any questions, please contact Ms. Oshita at [Cynthia.Oshita@oehha.ca.gov](mailto:Cynthia.Oshita@oehha.ca.gov) or at (916) 445-6900.

#### References

U.S. EPA ((U.S. Environmental Protection Agency) (2011a). Trichloroethylene (CASRN 79-01-6). Integrated Risk Information System. Available online at: <http://www.epa.gov/iris/subst/0199.htm>

U.S. EPA (U.S. Environmental Protection Agency) (2011b). Toxicological Review of Trichloroethylene (CAS No. 79-01-6); In Support of Summary Information on the Integrated Risk Information System (IRIS). EPA/635/R-09/011F U.S. EPA, Washington D.C., September 2011. Available online at: <http://www.epa.gov/iris/toxreviews/0199tr/0199tr.pdf>

<sup>1</sup> Commonly known as Proposition 65, the Safe Drinking Water and Toxic Enforcement Act of 1986 is codified in Health and Safety Code section 25249.5 *et seq.*

<sup>2</sup> See Health and Safety Code section 25249.8(b) and Title 27, Cal. Code of Regs. section 25306.

<sup>3</sup> Health and Safety Code section 25249.8(b)

<sup>4</sup> All referenced sections are from Title 27 of the Cal. Code of Regulations.

<sup>5</sup> Health and Safety Code section 25249.12 and Title 27, Cal. Code of Regs. Section 25102(o).

#### Flex Your Power Website



Energy efficiency and conservation information. Find incentives/rebates, technical assistance, retailers, product guides, case studies and more.

#### AMBER ALERT: Save a Child



AMBER ALERT empowers law enforcement, the media and the public to combat abduction by sending out immediate information.

OEHHA is one of five agencies under the umbrella of the California Environmental Protection Agency (Cal/EPA).

Air Resources Board | Department of Pesticide Regulation | Department of Toxic Substances Control  
Office of Environmental Health Hazard Assessment | State Water Resources Control Board

Conditions of Use/Privacy Policy  
 Copyright © 2007 OEHHA

